SEP 2 0 2005

Venaflo II Vascular Graft
510(k) Summary of Safety and Effectiveness
21 CFR 807.92(a).

General Information:

Submitter Name:	Bard Peripheral Vascular, Inc.
Address:	1625 W. Third Street P. O. Box 1740 Tempe, AZ 85280-1740
Telephone Number:	(480) 894-9515 ext. 2836
Fax Number:	(480) 449-2546
Contact Person:	Glenn Norton
Date of Preparation:	August 19, 2005

Device Information:

Device Name:	**Venaflo™ II Vascular Graft**
Trade Name:	**Venaflo™ II**
Common/Usual Name:	Arteriovenous Vascular Graft
Classification Name:	74 DSY – Prosthesis, Vascular Graft, Of 6mm and Greater Diameter 21 CFR 870.3450 - Class II Vascular graft prosthesis
Classification Panel:	Cardiovascular

Predicate Device:

IMPRA Venaflo™ Vascular Graft, K981079, concurrence date 05/07/1998.

Summary of Change:

The Venaflo Vascular Graft is being modified with printed trim lines on a more smoothly contoured venous cuff profile to enhance the good hemodynamic performance of the predicate design. All other aspects of the modified device remain the same as the predicate device. The changes optimize venous cuff sizing for the clinician when trimming the cuff for veins 8mm and smaller, and improve hemodynamic performance at the venous anastomosis.

Device Description:

Venaflo II arteriovenous vascular grafts have a pre-formed venous cuff to promote good hemodynamic performance at the venous anastomosis. Venaflo II grafts are

available in various lengths and diameters, in straight and stepped configurations, with and without external support.

Intended Use of Device:

Venaflo™ II Vascular Grafts are indicated for use as subcutaneous arteriovenous conduits for blood access only.

Technological Comparison to Predicate Device:

The technological characteristics of Venaflo II vascular grafts are substantially equivalent to those of the predicate Venaflo vascular graft in terms of intended use, application, user population, basic design, performance, labeling, packaging, and sterilization method.

Non-Clinical Performance Data:

Design verification of the modified device was done with conformance to or evaluated based on the following FDA Guidance and industry standards:

- *Guidance Document for Vascular Prosthesis 510(k) Submissions*, dated 11/01/2000
- ANSI/AAMI VP20-1994, *Cardiovascular Implants – Vascular Prosthesis*
- ANSI/AAMI/ISO 7198: 1998/2001, *Cardiovascular implants – Tubular vascular implants*
- AAMI/ANSI/ISO 10993-1: 1997, *Biological evaluation of medical devices – Part 1: Evaluation and testing, and the FDA Modified ISO 10993 Test Profile*
- AAMI/ANSI/ISO 10993-7: 1995, *Biological evaluation of medical devices – Part 1: Ethylene Oxide Sterilization Residuals*
- AAMI/ANSI/ISO 11135:1994, *Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization*

All test results confirm the modified device to be substantially equivalent to the predicate device.

Conclusions:

Venaflo II Vascular Grafts met all predetermined acceptance criteria of design verification and validation as required by the risk analysis, and as specified by applicable standards, guidance's, test protocols and/or customer inputs. Venaflo II Vascular Grafts are substantially equivalent to the legally marketed predicate device, the Venaflo Vascular Graft, K981079, concurrence date May 5, 1998.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 0 2005

Bard Peripheral Vascular, Inc.
c/o Mr. Glenn Norton
1625 W. Third Street
P.O. Box 1740
Tempe, AZ 85280-1740

Re: K052282
Venaflo™ II Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis of Less than 6MM Diameter
Regulatory Class: Class II (two)
Product Code: DSY
Dated: August 19, 2005
Received: August 23, 2005

Dear Mr. Norton:

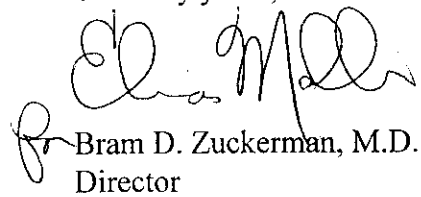
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 1-B

Venaflo™ II Vascular Graft
Special 510(k)

INDICATION(S) FOR USE STATEMENT*

I state in my capacity as Regulatory Affairs Associate Project Manager of Bard Peripheral Vascular, Inc., that this notification [510(k)] for the Venaflo™ II Vascular Graft is indicated for the following:

" *Venaflo ™ II* Vascular Grafts are indicated for use as subcutaneous arteriovenous conduits for blood access only."

Signature of 510(k) Submitter: _____

Printed Name of Submitter: Glenn Norton

Date: 8/19/05

*Suggested language and format to meet the requirements of sections 513(i) of the Federal Food, Drug, and Cosmetic Act, as amended, and sections 807.92(a)(5) and 801.4 of the Code of Federal Regulations, Title 21.

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K052282

510(k) Number K052282

Division Sign-Off _____
Office of Device Evaluation